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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,802	02/09/2005	Mathias Locher	42804-212835	6177

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EXAMINER	
BROOKS, KRISTIE LATRICE	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,802	LOCHER ET AL.	
	Examiner	Art Unit	
	Kristie L. Brooks	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 Feburary 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/09/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-15 are pending.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Specification

3. The disclosure is objected to because of the following informalities: The use of the trademark AVICEL ® has been noted in this application. It should be accompanied by a ® symbol or capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Note: Since no separate abstract was accompanied with this application, an abstract based on the WO2004/019984 publication will be made in the case of allowance. If applicant decides to use a different abstract, then one may be filed with the response to this Office Action.

Claim Rejections - 35 USC § 112/101

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 provide for the use of a glucocorticoid and at least one phosphodiesterase-4 inhibitor for producing a medicament for the treatment and prophylaxis of respiratory diseases, allergic diseases, asthma and/or chronic obstructive pulmonary diseases, but, since the claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper

process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4,6-8, and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Barsig (US Pub No. 2003/00992706).

The claims are dawn to a medicament comprising a glucocorticoid and at least one phosphodiesterase-4 inhibitor.

Barsig teaches the combined administration of a PDE4 or PDE3/4 inhibitors, such as N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide also known as AWD-12-281, roflumilast, cilomilast,

and disease modifying anti-rheumatic drugs (DMARDs) or another anti-rheumatic or anti-arthritic drug, such as budesonide and mometasone furoate for the treatment of diseases including rheumatoid arthritis, acute and chronic airway disorders of various origins (allergic bronchitis, bronchial asthma, emphysema, COPD), adult respiratory distress syndrome (ARDS), dermatoses (especially of proliferative, inflammatory and allergic type), for example (see the entire article, especially the abstract, page 1 paragraph [001],[0017]-[0018]; page 2 paragraph [0019]-[0022]; page 3 paragraph [0030]-[0032]; page 4 paragraph [0033]; page 6 paragraph [0050]-0051]). The combined administration includes simultaneous, sequential or separate administration of the PDE4 or PDE3/4 inhibitor on the one hand and the DMARD on the other hand, where the medicaments containing the PDE inhibitor and the DMARD are employed in the form of tablets, capsules, patches, suppositories, suspensions or solutions either together or separately and can be formulated with various excipients or vehicles suitable for desired pharmaceutical formulations (see the entire article, especially page 6 paragraph [0050-0053]; page 7 paragraph [0054]). The combined use (i.e. simultaneous, sequential or separate administration) of the PDE4 or PDE3/4 inhibitor and a DMARD may also include a medicament pack containing both the PDE4 or PDE3/4 inhibitor and a DMARD as discrete separate dosage forms and instructions for the simultaneous, sequential or separate administration of both discrete separate dosage forms (see the entire article, especially paragraph [0017]-[0020] and claims 1-6). Thus, the claims are readily envisioned by the composition taught by the reference.

8. Claim 1,3,5,6,8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO2000/028979) (for convenience, US 6,645,446 was used in the following rejection for translation purposes).

The claims are dawn to a composition comprising a glucocorticoid and at least one phosphodiesterase-4 inhibitor, where the glucocorticoid is loteprednol etabonate.

Keller et al. teaches dry powder formulations comprising one or more pharmaceutically active compounds such as corticosteroids (e.g. budesonide, ciclesonide, mometasone, fluticasone, beclomethasone, loteprednol) and phosphodiesterase inhibitors (e.g. piclamilast), where the active ingredients may also be available in the form of the pharmaceutically acceptable ester, for example, an etabonate (see the entire article, especially column 6 lines 11-51). The dry powder formulations can also contain inactive excipients and carriers (see the entire article, especially column 7 lines 23-53; column 8 lines 1-45). Thus, the claims are readily envisioned by the composition taught by the reference.

With respect to the 102(b) art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, for treatment of respiratory diseases, allergic diseases, asthma and/or chronic pulmonary diseases, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use

must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:00am-5:30pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB.
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VICKIE KIM
PRIMARY EXAMINER